DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 12, 2015

Davol Incorporated
Ms. Christine Lloyd
Regulatory Affairs Specialist
100 Crossings Boulevard
Warwick, Rhode Island 02886

Re: K142873
Trade/Device Name: OptiFix™ Absorbable Fixation System
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: February 6, 2015
Received: February 9, 2015

Dear Ms. Lloyd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142873

Device Name
OptiFix™ Absorbable Fixation System

Indications for Use *(Describe)*
The OptiFix™ Absorbable Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

I. SUBMITTER

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Date Prepared: March 12 2015

II. DEVICE

Name of Device:	OptiFix™ Absorbable Fixation System [product ordering codes 0113126 (deployment device contains 30 fasteners) and 0113127 (deployment device contains 15 fasteners)]
Common or Usual Name:	Staple Implantable/Implantable Staple
Classification Name:	Implantable staple (21 CFR §878.4750)
Regulatory Class:	II
Product Code:	GDW

III. PREDICATE DEVICE

OptiFix™ Absorbable Fastener System, K132134; marketed by Davol, Inc.,
This predicate has not been subject to a design-related recall.

The reference device Davol Absorbable Fastener System - SorbaFix™ (K082396) is used in this submission.

IV. DEVICE DESCRIPTION

The OptiFix™ Absorbable Fixation System is a sterile (via gamma) single use product that is comprised of a deployment component and an absorbable fastener component. Two product ordering codes are to be packaged for distribution; each contains the same ergonomically designed deployment device. The variation will be the preloaded fasteners; either 15 or 30. The shaft of the OptiFix™ Absorbable Fixation System is 39 cm in length and is designed for use with 5mm trocars. The fasteners are designed with retention features and are manufactured from Poly (D, L)-lactide.

V. INDICATIONS FOR USE

The OptiFix™ Absorbable Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

The Indications for Use statement for the subject device is identical to the predicate device. Both the subject and predicate devices have the same intended use for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair using the mechanical actuation (trigger) force to guide the fastener and launch the implant is the principle for both the proposed and predicate devices.

At a high level, the proposed and predicate devices are based on the following same elements:

- Deployment component – mechanical component used to guide the fastener into tissue
- Use of a mechanical component for positioning and launching the implant
- User-controlled mechanical trigger to guide the fastener (implant)
- Fastener component – absorbable component based on the same material used to fixate surgical mesh to tissue

At a high level, the following differences exist between the proposed and predicate devices:

- The proposed deployment device has a resistive trigger and the predicate has a rotating trigger.
- The proposed fastener component has slight differences in geometry than the predicate.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Performance standards

No performance standards have been established for this device under Section 514 of the Federal Food, Drug, and Cosmetic Act.

Biocompatibility testing
The biocompatibility evaluation for the OptiFix™ Absorbable Fixation System was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "*Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*," May 1, 1995, and International Standard ISO 10993-1 "*Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process*," as recognized by FDA.

Testing for the fastener included Cytotoxicity and the complete biocompatibility profile for the OptiFix fastener has been supported by full biocompatibility testing on the reference device, SorbaFix (K082396) as listed in the following. The fastener materials between the OptiFix and the reference device have been demonstrated to be substantially equivalent.

- Sensitization
- Intracutaneous Reactivity
- Single-dose Systemic Toxicity
- Rabbit Pyrogenicity
- 14-Day Repeat Dose Intravenous Toxicity
- Genotoxicity
- Chronic Toxicity, 13 weeks
- Implantation, 52 weeks

Testing for the new materials within the deployment device included Cytotoxicity, Sensitization, Intracutaneous Reactivity, and Single-dose Systemic Toxicity.

The deployment component of the proposed OptiFix™ Absorbable Fixation System is determined to be tissue contacting for duration of less than 24 hours, while the absorbable fasteners are determined to be permanent implants.

Testing
The following non-clinical tests were completed for the proposed and predicate device. The OptiFix™ Absorbable Fixation System passed all the test requirements and demonstrated substantial equivalence to the test results of the predicate device.

- Performance and Functional testing of the OptiFix™ Absorbable Fixation System-deployment device and fastener
  - Actuation (trigger) torque
  - Fastener deployment
  - Fastener gap height
  - Ball burst testing
- Mesh compatibility testing of the OptiFix™ Absorbable Fixation System
- Resorption profile of the fastener

All samples tested met the established acceptance criteria.

Animal Study

Animal studies were not performed on the proposed device for this submission. Based on identical materials and comparable mechanical strengths measured at the bench level, the in vivo safety and performance of the proposed device was evaluated via the animal and histological studies conducted on the reference device, the SorbaFix Fixation Device.

Clinical Studies

Clinical studies were not performed for the submission of this device nor were clinical studies performed for the predicate device.

Table 7-1: Device Substantial Equivalence – General Characteristics

Device Features	Proposed device OptiFix™	Predicate device OptiFix™ (K132134)
Intended Use	Soft tissue fixation	Soft tissue fixation
Indication For use	Indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.	Indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.
Fastener Material	Poly (D,L) Lactide	Poly (D,L) Lactide
Fastener Violet Dye	D & C Violet No. 2 conforms to 21 CFR §74.3602	D & C Violet No. 2 conforms to 21 CFR §74.3602
Fastener Body Contact	Long term implant (>30 days) contacting tissue and/or bone	Long term implant (>30 days) contacting tissue and/or bone
Fastener Shape/Design	Push Tack with retention features on end	Push Tack with retention features on end
Fastener Dimensions	6.7 mm overall fastener length Fastener head: 3.7 mm length; 3.5 mm thickness	6.7 mm overall fastener length Fastener head: 3.7 mm length; 3.5 mm thickness
Fastener Manufacturing Method	Injection-Molded	Injection-Molded
Fastener Absorption Time	360 days	360 days
Fastener Quantity per Device	15 & 30 fasteners	15 & 30 fasteners

Device Features	Proposed device OptiFix™	Predicate device OptiFix™ (K132134)
Fastener Delivery System	Push – Impact tube pushes fasteners forward over a straight guidewire	Push – Impact tube pushes fasteners forward over a straight guidewire
Deployment Device Handle design	Pistol/Gun shape	Pistol/Gun shape
Deployment Device Shaft Nominal Length	39 cm in length	39 cm in length
Deployment Device Trigger	Resistive trigger	Rotating trigger
Deployment Device Trigger Stroke	Swift and full	Slow and progressive
Deployment Device Guidewire	Moveable	Stationary
Device Sterilization	Gamma Irradiation (25 - 40 kGy)	Gamma Irradiation (25 - 40 kGy)

VIII. CONCLUSIONS

The OptiFix™ Absorbable Fixation System is substantially equivalent to the legally marketed predicate device for the following reasons:

A) The same intended use and indications for use as the predicate device.
B) Both devices use a similar fixation technology to deliver the fasteners by compressing a trigger.
C) Both devices house similar synthetic absorbable fastener with retention head design.
D) Identical materials with long history of biocompatible use in medical instrumentation and implantation.
E) Identical technological characteristics to the predicate devices such as: Fastener dimensions trigger handle, penetration depth, and shaft length.
F) Same principle of operation.

The comparative analysis as well as the bench and preclinical testing results demonstrated that the OptiFix™ Absorbable Fixation System should perform as safe, and as effective, as the predicate device that is currently marketed for the same intended use.